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| 10/665,514 | 09/22/2003 | Marius Hauri | 0100/0165 | 5820 |
| 21395 | 7590 | 04/15/2008 | | |
| LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314 | | | EXAMINER WITCZAK, CATHERINE | |
| | | | ART UNIT 3767 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|-------------------------------------|--|
| Office Action Summary | Application No. 10/665,514 | Applicant(s) HAURI ET AL. | |
| | Examiner Catherine N. Witczak | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,13-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, 13-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 4, 9, 20-21, 23, & 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Crawford et al (US Pub. No. 2002/0161336A1). The Crawford reference discloses a safety apparatus in figures 1-14 comprising a needle hub 60 having a proximal portion and a distal portion, a needle 40 extending from a distal end of said needle hub; a collar 90 rotatably mounted directly on the distal portion of said needle hub, said collar having a first engage mechanism 97 at its inner circumferential surface; a housing 140 pivotally connected to said collar; and a needle sheath 50 having a proximal portion with a second engage mechanism 56 at its outer circumferential surface, said first and second engage mechanism fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said needle hub when said sheath is fitted to said collar and said first and second engage mechanism are engaged to each other.

With respect to claims 2 & 21, see figure 12.

With respect to claims 4 & 23, wherein second engage mechanism 56 comprises a groove and first engage mechanism 97 comprises a rib, see figures 2, 9, & 10.

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With respect to claims 9 & 28, wherein the collar has a lock mechanism 118 and wherein the housing has an other lock mechanism 194 for coacting to fixedly retain the housing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Landis (US Patent No. 5490841). The Crawford reference discloses the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening in figures 9A-B & 11. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Crawford in order to easily entrap the needle with the housing.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Gyure (US Patent No. 5669889). The Crawford reference discloses the claimed invention except for lock mechanisms on the collar and housing utilizing an aperture. The Gyure reference teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61,57, figure 3). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure in

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the apparatus of Crawford in order to provide a lock mechanism for one-way safety locking to prevent re-exposure of the needle after covering.

4. Claims 5 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Johnson (US Pub. No. 2002/0010433). The Crawford reference discloses the claimed invention except for a ring spaced around the hub end for a user to grasp. The Johnson reference teaches a ring spaced around a hub end for a user to grasp (figures 2a-e). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Johnson in the apparatus and method of Crawford in order to facilitate connection of the hub and barrel.

5. Claims 6 & 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al (US Pub. No. 2002/0161336A1) as applied to claims 1 & 20 and further in view of Pressly, Sr. et al (US Patent No. 7014622 B1). Now even though Crawford does not explicitly disclose a window attention is directed to Pressly. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see figure 10 and col. 7 lines 35-43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Crawford in view of Pressly in order to provide a window via a transparent ring in order to see if the device has been properly connected.

6. Claims 11, 13-17, & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US Pub. No. 200210010433) in view of Crawford et al (US Pub. No. 2002/0161336A1) and further in view of Pressly, Sr. et al (US Patent No. 7014622 B1). The Johnson reference discloses a needle hub with a luer connector 68 and a ring 42 graspable by a user to remove the needle hub from a syringe

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surrounding, in a spaced relation, to the luer connector, see figures 2A-F. Now even though Johnson does not explicitly disclose a collar and a needle sheath attention is directed to Crawford. The Crawford reference teaches a needle hub 60 having a luer connector and a needle 40 on the distal end of the hub; a collar 90 having a housing 140 pivotally connected thereto directly fitted to and rotatable about said distal portion of the needle hub, and a needle sheath 50 having a proximal portion with only one side in contact engagement to said collar, said needle sheath not in contact with said needle hub and removable from said collar to expose said needle for use. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson with the teachings of Crawford in order to provide a shielding apparatus to help prevent accidental punctures by the needle. Now even though Johnson does not explicitly disclose a window in the ring, attention is directed to Pressly, Sr. et al. The Pressly, Sr. et al reference teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of the needle hub, see figure 10 and col. 7 lines 35- 43, wherein the transparency would be deemed a window. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Johnson in view of Pressly in order to provide a window via a transparent ring in order to see if the device has been properly connected. Also see rejection above with respect to Crawford.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US Pub. No. 2002/0010433) in view of Crawford et al (US Pub. No. 2002/0161336A1) in view of Pressly, Sr. et al (US Patent No. 7014622 B1) as applied to claim 11 and further in view of Landis (US Patent No. 5490841). The Johnson in view of Crawford reference discloses the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening in figures 9A-B & 11. It would have been obvious to one of ordinary skill in

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the art at the time of the invention to use the teachings of Landis in the apparatus in order to easily entrap the needle with the housing.

Allowable Subject Matter

Claims 7 & 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 11, 13, & 15-17 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed 12/18/06 have been fully considered but they are not persuasive. Applicant argues that the Crawford reference does not disclose a collar rotatable about the needle hub, Examiner again disagrees. The Crawford reference states that the collar may be mounted to the needle hub via mechanical fit and wherein it is the examiner's position that the collar is still fully capable of being rotated about the needle hub since it does not necessarily have to be welded or bonded onto the device. Applicant argues that Crawford does not disclose the circumferential groove and rib, the Examiner again disagrees. The helical thread and corresponding thread would both indeed disclose a rib and a circumferential groove, which would be the thread and the area between the threads respectively. Due to the lack of definition of the terms in the specification, it is the examiner's position that under the broadest reasonable interpretation the helical thread and groove is a circumferential groove and rib. Applicant argues that Landis does not teach lips "angled toward the interior of the housing with the respective angles of said lips being varied along the length of the housing to effect guide for said needle to smoothly enter into said housing at an angle through said opening", the Examiner again disagrees. The Landis reference discloses such lips in figures 9A-B & 11.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witezak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cw
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767